

## ***Remarks***

### ***Support for the Amendments***

Support for the foregoing amendments to claims 1, 3, 4, 16 and 17 can be found throughout the specification. These amendments do not add new matter, and their entry and consideration are respectfully requested.

### ***Status of the Claims***

By the foregoing amendments, claims 1, 3, 4, 16 and 17 are sought to be amended. Upon entry of the foregoing amendments, claims 1, 3-9 and 15-17 are pending in the application, with claims 1, 3 and 4 being the independent claims.

### ***Summary of the Office Action***

In the Office Action dated November 18, 2003, the Examiner has made three rejections of the claims. Applicants respectfully offer the following remarks to traverse each of these elements of the Office Action.

### ***The Rejection Under 35 U.S.C. § 102(b) Over Banholzer***

In the Office Action at page 3, the Examiner has rejected claims 4-7, 16 and 17 under 35 U.S.C. § 102(b), as allegedly being anticipated by Banholzer *et al.* (*Mol. Cell. Biol.* 17:3254-3260 (1997); hereinafter "Banholzer"). Applicants respectfully traverse this rejection.

The Examiner contends that Banholzer discloses "an expression construct comprising a gene encoding a protein, 5' and 3' UTR sequences comprising control elements

and instability sequences, wherein the 3' UTR comprising the instability sequence is inserted into the construct." *See* Office Action, at page 3. The Examiner further contends that the presently claimed construct has the same elements as the construct disclosed in Banholzer. Applicants respectfully traverse these contentions.

Present claims 1, 3 and 4 (and hence, claims 5-7, 16 and 17 that depend ultimately therefrom) all recite that the instability region is heterologous to the 3' UTR sequence.

Banholzer does not disclose an instability region that is inserted into the 3' UTR of the expression cassette and that is heterologous to the 3' UTR sequence. Hence, Banholzer does not disclose all of the elements of the presently claimed invention.

Under 35 U.S.C. § 102, a claim can only be anticipated if every element in the claim is expressly or inherently disclosed in a single prior art reference. Since Banholzer does not expressly or inherently disclose one or more elements of the presently claimed invention, this reference cannot and does not anticipate claims 4-7, 16 and 17. Therefore, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) over Banholzer is respectfully requested.

***The Rejection Under 35 U.S.C. § 103(a) Over Banholzer and Zhang***

In the Office Action at pages 3-5, the Examiner has rejected claims 1, 3 and 15 under 35 U.S.C. § 103(a), as being unpatentable over Banholzer in view of Zhang *et al.* (*Biochem. Biophys. Res. Comm.* 227:707-711 (1996); hereinafter "Zhang"). Applicants respectfully traverse this rejection.

Claims 1 and 3 (and hence claim 15 that depends ultimately from claim 1) recite that the instability region is heterologous to the 3' UTR sequence. The serious deficiencies in

Banzholzer discussed previously are not cured by the disclosure of Zhang. Zhang does not disclose, suggest or contemplate the use of such a heterologous instability region. Hence, Applicants respectfully submit that the ordinarily skilled artisan would not have obtained the presently claimed invention by combining these two references.

In view of the foregoing remarks, Applicants respectfully assert that the Examiner has not established a *prima facie* case of obviousness, and hence claims 1, 3 and 15 would not have been obvious over the disclosures of Banholzer and Zhang, alone or in combination. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) over Banholzer in view of Zhang therefore is respectfully requested.

***The Rejection Under 35 U.S.C. § 103(a) Over Danner and Banholzer in view of Maniatis***

In the Office Action at pages 5-7, the Examiner has rejected claims 8 and 9 under 35 U.S.C. § 103(a) as being unpatentable over Danner (*J. Biol. Chem.* 273:3223-3229 (1998); hereinafter “Danner”) and Banholzer in view of Maniatis (*Molecular Cloning, A Laboratory Manual*, p 16.33-16.17 (1989); hereinafter “Maniatis”). Applicants respectfully traverse the rejection.

As noted above, present claim 4 (and hence, claims 8 and 9 which depend ultimately therefrom) recites that the instability region is heterologous to the 3' UTR sequence. Banholzer does not disclose such a system. Danner also does not disclose such a system. These serious deficiencies in Danner and Banholzer are not cured by the disclosure of Maniatis, as Maniatis only discloses a method of stably transfecting cells.

Hence, the disclosures of Danner, Banholzer and Maniatis, alone or in combination, cannot render obvious the presently claimed invention. In view of the arguments presented

above, Applicants submit that the Examiner has not established a *prima facie* case of obviousness, and therefore reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

***Other Matters***

Applicants thank the Examiner for including copies of Information Disclosure Statement 1449 Forms pages 6 and 7 citing documents AR6-AT6 and AR7-AT7 with the present office action.

***Conclusion***

All of the stated grounds of rejection have been properly traversed. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn.

Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of

this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

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